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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,266	06/28/2000	Rama Akella	SBI-066	6018

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/13/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/605,266

**Applicant(s)**

AKELLA ET AL.

**Examiner**

Janet L. Andres

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 is/are allowed.
- 6) ☒ Claim(s) 1-21, 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 28 May 2002 is acknowledged. Claims 1-26 are pending in this application. Claim 22 is withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The rejection of claims 9-13 and 16-18 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections Maintained/New Grounds of Rejection***

4. The rejection of claims 1-5 under 35 U.S.C. 102(b) as anticipated by U.S. patent 5393739 is maintained for reasons of record in the office action of paper no. 7.

Applicant has amended the claims so that they are now drawn to a method of use.

Applicant argues that "wound healing" is distinct from osteogenesis.

Applicant's arguments have been fully considered but have not been found to be persuasive.

Stedman's Medical Dictionary, copyright © 2002 by Medical Economics Company, Inc. at Montvale, NJ 07645, defines a wound as

1. Trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity.

MPEP §2111.01 states,

Applicant may be his or her own lexicographer as long as the meaning assigned to the term is not repugnant to the term's well known usage. In re Hill, 161 F.2d 367, 73

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USPQ 482 (CCPA 1947). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multi-form Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998).

Thus, while Applicant may regard the healing of a fracture as distinct from the healing of a wound, the art does not, and Applicant has not provided any definition of a "wound" in the specification.

5. The rejection of claims 1-8 as unpatentable over U.S. patents 5459047 and 5543394 is maintained for reasons of record in the office action of paper no. 7.

As stated in the office action of paper no. 7, each of these patents teaches compositions comprising BMPs and TGF- $\beta$ . Further, each of these patents teaches that such compositions may be used to promote wound healing. Thus, the patents clearly anticipate claims drawn to the use of BMP/TGF- $\beta$  mixtures to promote wound healing.

Applicant argues that these two patents teach only that BMP mixtures "may" be used for wound healing, not that they are actually useful for this purpose. Applicant argues that there is no example or specific teaching that those proteins are actually capable of being used for wound healing. Applicant argues that Applicant's specification indicates that the field is unpredictable. Applicant further argues that neither patent teaches the use of the composition of claim 6 or the ribosome-free composition of claim 7, and further that neither teaches or suggests the importance of phosphorylation or glycosylation.

Applicant's arguments have been fully considered but have not been found to be persuasive. Each of these patents clearly teaches that the claimed compositions would be useful for wound healing. "May" is used in a permissive, rather than a conditional sense; the patents similarly teach that the compositions "may" be used for bone growth. Applicant has not

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established a *prima facie* case that these patents are not enabling: no fact or evidence is supplied to explain why one of ordinary skill would not believe teachings of the patents. Applicant points to pages 2-4 of the instant specification, but none of the examples provided describes the effects of the combinations set forth in the patents.

Applicant further argues that neither patent teaches the use of the composition of claims 6 or 7, or teaches the importance of phosphorylation or glycosylation. However, recombinant proteins would inherently be free of ribosomal or histone contamination, and factors purified from natural sources would inherently be at least partially phosphorylated or glycosylated. Both processes of producing proteins are well known to one of ordinary skill in the biochemical arts. Further, each of the patents teaches compositions comprising BMP-2, BMP-3, BMP-6, and TGF- $\beta$ : see column 2 of the '394 patent and columns 7 and 8 of the '047 patent. Neither patent explicitly discloses TGF- $\beta$ 2. However, as there are only three human TGFs-  $\beta$  known, one of ordinary skill could easily envision a particular member of the genus. See MPEP §2144.08. Thus, the patents teach compositions comprising those used by Applicant, and teach the methods claimed by Applicant.

6. The rejection of claims 9-12 under 35 U.S.C. 102(b) as anticipated by U.S. patent 5290763, U.S. patent 5563124, and U.S. patent 5371191 is maintained for reasons of record in the office action of paper no. 7 and applied to new claim 25.

Applicant has amended the claims so that they are drawn to methods of treatment. Applicant argues that none of the above patents teaches wound healing. Applicant additionally argues that none of the patents teaches further purification of the compositions, nor do they teach phosphorylation or glycosylation.

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Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, Applicant has provided no definition of "wound healing" and the art-standard definition of a wound does not exclude injuries to bone. Thus, the amended claims do not distinguish over the patents. Further, products purified from nature would inherently be glycosylated and phosphorylated, as discussed above. Since the products have been purified through gel electrophoresis, they are also free of contaminating ribosomal proteins or histones.

7. The rejection of claims 1-8 under 35 U.S.C. 102(e) as anticipated by U.S. patent 6150328 is maintained for reasons of record in the office action of paper no. 7.

Applicant argues that this reference is only an invitation to experiment, because the patent teaches only that the compositions "may" be used for wound healing.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, "may" is used in the permissive sense in the patent, which similarly states that the compositions "may" be used for bone growth. Because the instant claims are drawn to methods using compositions comprising BMP-3 and TGF- $\beta$ , they are anticipated by a patent that disclosed that compositions containing these factors as well as others are useful in wound healing. It would not merely be "obvious to try" to use the compositions; the patent clearly states that they may be so used. Applicant's statement that wound healing is unpredictable does not provide a *prima facie* case of non-enablement; no fact or evidence that would form the basis for doubting the statements in the patent is set forth.

8. The rejection of claims 13-18, 20, and 23 under 35 U.S.C. 103(a) as unpatentable over U.S. patent 6150328 in view of U.S. patents 5393739 and 4950483 is maintained for reasons of record in the office action of paper no. 7.

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Applicant argues that there are no examples in the '328 patent that show that BMPs promote wound healing. Applicant further argues that the '483 patent does not teach BMPs. Applicant argues that the '739 patent teaches does not teach wound healing, and that osteogenesis is a different process.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, the '328 patent teaches that BMPs are useful for wound healing. Thus, one of ordinary skill in the art would expect that they could be used for this purpose. The patent states that they are, and Applicant has provided no teachings as to why one of ordinary skill would not conclude that they were. It is further not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art (*In re Keller*, 642 F.2d 413, 288 USPQ 871 9ccpa 1981). Each of these patents teaches factors useful for wound healing, and it would have been *prima facie* obvious to one of ordinary skill to combine them; one of ordinary skill would expect that the combination would also be useful. In addition, also as stated above, a "wound" as defined by Steadman's Medical Dictionary encompasses any tissue, including bone, and Applicant has not provided any definition by which one of ordinary skill in the art would understand Applicant's special meaning. One of ordinary skill would consider osteogenesis and the healing of fractures to be "wound healing".

9. The rejection of claims 19 and 21 under 35 U.S.C. 103(a) as unpatentable over U.S. patents 539739 and 4950483 in view of U.S. patent 4950273 is maintained for reasons of record in the office action of paper no. 7. Applicant argues that including a hydrogel would not support

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a reasonable expectation of success.

Applicant's arguments have been full considered but have not been found to be persuasive. As stated above, the '739 and '483 patents teach compositions for wound healing. Applicant has provided no teachings as to why one of ordinary skill would not expect that the compositions could be used as disclosed in these patents.

10. The rejection of claim 24 under 35 U.S.C. 103(a) as unpatentable over U.S. patents 6150328, 5393739, and 4950483 in view of U.S. patent 5616490 is maintained for reasons of record in the office action of for reasons of record in the office action of paper no. 7.

Applicant argues that including TNF- $\alpha$  would not support a reasonable expectation of success.

Applicant's arguments have been full considered but have not been found to be persuasive. As stated above, the '328, '739 and '483 patents teach compositions for wound healing. Applicant has provided no teachings as to why one of ordinary skill would not expect that the compositions could be used as disclosed in these patents.

***Allowable Subject Matter***

11. Claim 25 is allowed because the prior art neither teaches nor suggests the use of the particular composition encompassed for the particular form of wound healing claimed.

CLAIMS 1-21, 23 AND 24 ARE REJECTED. CLAIM 25 IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly

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set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

August 7, 2002

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is fluid and elegant, with a large loop at the beginning of the first name.

LORRAINE SPECTOR  
PRIMARY EXAMINER